K072184

510(k) SUMMARY

SEP 18 2007

VITOSS® BIOACTIVE FOAM BONE GRAFT SUBSTITUTE

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Orthovita, Inc.
45 Great Valley Parkway
Malvern, PA 19355

Phone: (610) 640-1775

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Contact Person: Gina M. Nagvajara, Ph.D.
V.P., Regulatory Affairs

Date Prepared: August 3, 2007

Common or Usual Name – Vitoss® Bone Graft Substitute- Bioactive Foam Strip, Vitoss® BA Bone Graft Substitute- Bioactive Foam Strip, Bone Graft Substitute

Classification Name – Bone Void Filler

Product Code - MQV

Predicate Devices

1. Orthovita, Inc. – Vitoss Scaffold Foam Bone Graft Substitute (K032288)
2. NovaBone – NovaBone Bioactive Synthetic Graft (K052494)
3. NovaBone –NovaBone Putty Bioactive Synthetic Graft (K060728)
4. Nanotherapeutics – Origen DBM with Bioactive Glass (K062459)

Intended Use / Indications for Use

Vitoss® Bioactive Foam Bone Graft Substitute is labeled with the following Intended Use statement:

Vitoss Bioactive Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. *Vitoss* Bioactive Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. *Vitoss* Bioactive Foam should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.

Vitoss Bioactive Foam Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Technological Characteristics

Vitoss Bioactive Foam is a resorbable, osteoconductive implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone.

Performance Data

Performance testing was conducted to ensure that *Vitoss* Bioactive Foam met its design specifications and performed in a manner substantially similar to the predicate devices. In all instances, *Vitoss* Bioactive Foam functioned as intended.

Vitoss Bioactive Foam is osteostimulatory based on in-vitro studies in which calcium phosphate growth was induced on the surface of the *Vitoss* Bioactive Foam after exposure to simulated body fluid. The *Vitoss* Bioactive Foam strips had widespread calcium phosphate formation by 3 days. This phenomenon was not observed in control samples in which there was no bioactive glass component. The osteostimulatory nature of *Vitoss* Bioactive Foam has not been correlated to human clinical experience.

Substantial Equivalence

Vitoss Bioactive Foam is as safe and effective as its predicates. *Vitoss* Bioactive Foam has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences between *Vitoss* Bioactive Foam and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that *Vitoss* Bioactive Foam is as safe and effective as its predicate devices. Thus, *Vitoss* Bioactive Foam is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthovita, Inc.
% Gina M. Nagvajara, Ph.D.
V.P., Regulatory Affairs
45 Great Valley Parkway
Malvern, PA 19355

SEP 18 2007

Re: K072184
Trade/Device Name: Vitoss® Bone Graft Substitute-Bioactive Foam Strip,
Vitoss® BA Bone Graft Substitute- Bioactive Foam Strip,
Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: August 3, 2007
Received: August 6, 2007

Dear Dr. Nagvajara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: *Vitoss*® Bioactive Foam Bone Graft Substitute

INDICATIONS FOR USE:

Vitoss Bioactive Foam Bone Graft Substitute is labeled with the following Intended Use statement:

> *Vitoss* Bioactive Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. *Vitoss* Bioactive Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. *Vitoss* Bioactive Foam should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously.
>
> *Vitoss* Bioactive Foam Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bull

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072184